

REMARKS

Claims 1, 3-6, 8, 11 and 12, 20-24 currently appear in this application. The Office Action of May 28, 2008, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicant respectfully requests favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Claims 1, 3, 4, 11, 12, 19-21 and 24 are rejected under 35 U.S.C. 102(b) as anticipated by Bohr et al., US 6,060,293.

This rejection is respectfully traversed. The limitations of claim 2 have been incorporated into claim 1. Claim 2 has not been rejected as being anticipated by Bohr, so it is respectfully submitted that the remaining claims are no longer anticipated by Bohr.

Bohr is entirely different from the method claimed herein. In Bohr, electromagnetic radiation such as microwaves is applied to chain molecules such as a protein in order to change the structure of the molecule. In the method of Bohr, high frequency energy of electromagnetic waves is applied to a chain molecule, whereby the chemical bonds in the molecule are rotated and/or vibrated, resulting in a change in the three-dimensional structure of the molecule. This is clearly shown

in the abstract, and at column 3, line 66 to column 4, line 15 and column 6, lines 46-53. In fact, Bohr even notes that the method can result in denaturation of peptides, polypeptides, and proteins (abstract, lines 1-8). One skilled in the art, reading Bohr would not believe that applying electromagnetic radiation such as microwaves and radiowaves or ultra sound to chain molecules could be used to stabilize these molecules, as claimed herein.

On the other hand, the method claimed herein is for storing a recombinant protein solution formulation under a magnetic field in order to stabilize the protein formulation. Under these conditions, frequency energy as applied in Bohr is not applied to the protein molecules in the herein claimed process. For example, as shown in the working example of the present application, stabilization of a protein formulation is achieved by storing the formulation with a magnet. No frequency energy is applied from the magnet, since the magnet produces a magnetic field in the vicinity of the magnet, but does not produce electromagnetic waves such as microwaves.

Accordingly, it is respectfully submitted that storing a protein formulation under a magnetic field, which is constant, is technically different from applying an electromagnetic wave to a protein formulation.

The difference between a magnetic field and electromagnetic waves can also be seen from the difference between the units used to express them. Namely, tesla (T) is used for a magnetic field. On the other hand, Hertz (Hz) is used for electromagnetic waves.

A Hertz is a measure of frequency, informally defined as the number of cycles occurring per second. A Tesla, on the other hand, is a measure of the flux density (or field intensity) of a magnetic field. A Tesla is not a measure of cycles per second, and, therefore, a magnetic field is not the same as an electromagnetic wave.

Claims 1-6, 11, 12, and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bohr et al. in further view of Plantanias et al., JCO 1991 and further support from Rosse et al., ASH, Hematology 2000.

This rejection is respectfully traversed. As noted above, there is nothing in Bohr regarding storing a protein formulation under a magnetic field. Bohr applies waves of electromagnetic radiation, rather than keeping the solution under a steady field. In fact, Bohr uses this wave energy to denature proteins, rather than to preserve proteins as claimed herein.

Neither Plantanias nor Rosse adds anything to Bohr, because none of these references has anything to do with

storing protein solution formulations under the influence of magnetic field.

Claims 1-6, 8, 11, 12 and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bohr in view of Cohen, US 3,308,809.

This rejection is respectfully traversed. The fact that Cohen discloses a pre-filled syringe adds nothing to Bohr. It is clear that Rohr applies electromagnetic wave energy to a protein formulation, while the presently claimed method maintains a protein formulation solution under the influence of a magnetic field.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

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